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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,550	11/13/2001	Geeta Saxena	SMAR-017CIP	1457

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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/03/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/992,550

Applicant(s)

SAXENA ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,5,6,8-33,35,36 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,7,34 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4, 10</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

This is a continuation-in-part of the US Serial No. 09/881,559, filed June 14, 2001.

Applicant's election of the invention of Group I, claims 1, 4, 7, and 23-37 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election of the specie of neoabietic acid, Compound (XIII) and autoimmune disease in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-38 are pending.

Claims 2-3, 5-6, 8-22, and 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Claims 23-33 and 35-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

The claims have been examined herein to the extent they read on the elected invention and species.

Claim Objections

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Claim 1 is objected to because of the following informalities: the use of abbreviation "RANTES" is improper. Appropriate correction is required. Examiner will favorably consider the whole term to be written out.

Claim 7 is objected to because of the following informalities: the use of abbreviation "NSCLC" is improper. Appropriate correction is required. Examiner will favorably consider the whole term to be written out.

Claim 7 is objected to because of the following informalities: the use of parenthesis in claim 7, line 1-3 from the last line: "(such as leukemias, ... lymphoma/leukemia)", is considered improper. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 7, 34, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The

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Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation describing R₁, R₂, and R₃ and R₄, R₅, and R₆ : "substituted or unsubstituted alkyls", and the claim also recites "substituted or unsubstituted C₁₋₁₀ alkyls; substituted or unsubstituted C₁₋₆ alkyls" which are the narrower statement of the range/limitation.

In addition, claim 1 recites the broad recitation describing R₁, R₂, and R₃ and R₄, R₅, and R₆ : "substituted or unsubstituted cycloalkyls", and the claim also recites "substituted or unsubstituted C₃₋₆ cycloalkyls" which are the narrower statement of the range/limitation.

In addition, claim 1 recites the broad recitation describing R₁, R₂, and R₃ and R₄, R₅, and R₆ : "substituted or unsubstituted alkenyls", and the claim also recites "substituted or unsubstituted C₂₋₆ alkenyls" which are the narrower statement of the range/limitation.

In addition, claim 1 recites the broad recitation describing R₁, R₂, and R₃ and R₄, R₅, and R₆ : "substituted or unsubstituted alkynyls", and the claim also recites "substituted or unsubstituted C₂₋₆ alkynyls" which are the narrower statement of the range/limitation.

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In addition, claim 7 recites the broad recitation "autoimmune disease", and the claim also recites "rheumatoid arthritis", "allograft rejection", "psoriasis", "inflammatory bowel disease", "Crohn's disease", "ulcerative colitis", "lupus nephritis", which are the narrower statement of the range/limitation.

In addition, claim 7 recites the broad recitation "arthritis", and the claim also recites "rheumatoid arthritis", "osteoarthritis", "acute gouty arthritis", which are the narrower statement of the range/limitation.

In addition, claim 7 recites the broad recitation "inflammatory bowel disease", and the claim also recites "Crohn's disease" and "ulcerative colitis", "lupus nephritis", which are the narrower statement of the range/limitation.

In addition, claim 7 recites the broad recitation "gout", and the claim also recites "acute pseudogout" and "acute gouty arthritis", which are the narrower statement of the range/limitation.

In addition, claim 7 recites the broad recitation "skin carcinoma", and the claim also recites "melanomas", which is the narrower statement of the range/limitation.

In addition, claim 7 recites the broad recitation "bone and soft tissue sarcoma", and the claim also recites "Kaposi's sarcoma", which is the narrower statement of the range/limitation.

In addition, claim 7 recites the broad recitation "tumors of the nerves", and the claim also recites "gliomas ... meningiomas", which are the narrower statement of the range/limitation.

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In addition, claim 7 recites the broad recitation "solid tumors arising from hematopoietic malignancies", and the claim also recites "leukemias ... lymphoma/leukemia", which are the narrower statement of the range/limitation.

In addition, claim 7 recites the broad recitation "tumors of the eyes", and the claim also recites "retinoblastomas", which are the narrower statement of the range/limitation.

The term "cardiovascular" in claim 7 renders the claims indefinite as to what diseases are encompassed by the claims.

Regarding claim 7, line 1-3 from the last line: the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The terms "solid tumors arising from hematopoietic malignancies" and "solid tumors arising from lymphomas" in claim 7 render the claims indefinite as to what tumor diseases are encompassed by the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4, 7, 34, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giuseppe (DE 3113460 from the IDS received January 14, 2003, English abstract is provided) in view of Moreland et al. (Am. J. Med. Sci., 1993; 305(1): 40-51), only the abstract is provided.

Giuseppe teaches a composition comprising neoabietic acid useful as a treatment for chronic diseases such as rheumatism and arthritis (See the English abstract, also page 2, paragraph 2).

Giuseppe does not expressly teach the employment of neoabietic acid in treating autoimmune diseases.

Moreland et al. teaches that rheumatoid arthritis is an autoimmune disease.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ Giuseppe's composition, which containing neoabietic acid, to treat rheumatoid arthritis, which is known to be an autoimmune disease.

One of ordinary skill in the art would have been motivated to employ the neoabietic acid containing composition to treat an autoimmune disease such as rheumatoid arthritis. Giuseppe's composition, which contains neoabietic acid, is known

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to be useful as treating chronic illnesses such as rheumatoid arthritis. Since rheumatoid arthritis is known to be an autoimmune disease, treating rheumatoid arthritis would be seen as treating autoimmune disease. Therefore, possessing the teaching of the cited prior art, employing the neoabietic acid containing composition to treat an autoimmune disease such as rheumatoid arthritis, would be reasonably expected to be effective.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



San-ming Hui
Patent Examiner
Art Unit 1617
May 29, 2003